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(Original Signature of Member)

116TH CONGRESS
2D SESSION

H. R. _____

To amend the Public Health Service Act to incentivize the manufacture of certain medicines in the United States and to enhance the security of the United States pharmaceutical supply chain, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. JOYCE of Pennsylvania introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to incentivize the manufacture of certain medicines in the United States and to enhance the security of the United States pharmaceutical supply chain, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Enhancing the Security of the U.S. Pharmaceutical Supply Chain Act of 2020''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. Identification, development, and procurement of priority medicines.
Sec. 4. Tax incentives for domestic manufacturing of priority medicines.
Sec. 5. Improving regulatory efficiencies for facility transfer of drugs.

SEC. 3. IDENTIFICATION, DEVELOPMENT, AND PROCUREMENT OF PRIORITY MEDICINES.

(a) PRIORITY MEDICINES.—Title XXVIII of the Public Health Service Act (42 U.S.C. 300hh et seq.) is amended by adding at the end the following:

"SEC. 2804. IDENTIFICATION OF PRIORITY MEDICINES.

"(a) PRIORITY MEDICINES.—The Secretary shall designate as a priority medicine each covered product that—

"(1)(A) is necessary for use in a public health emergency declared under section 319; or

"(B) is at high risk of becoming in short supply; and

"(2) has a vulnerable global supply chain.

"(b) GLOBAL SUPPLY CHAIN VULNERABILITY.—In determining whether a covered product has a vulnerable global supply chain under subsection (a)(2), the Secretary shall consider—

"(1) the findings of the National Academies of Sciences, Engineering, and Medicine in the report

published pursuant to section 4111 of the CARES Act (Public Law 116–136);

''(2) the number of manufacturers of each covered product;

''(3) the manufacturing locations, and amount produced, of each covered product;

''(4) the history of the importation of each priority medicine; and

''(5) the probability of the imposition of duties on the importation of each covered product.

''(c) CONSULTATION.—In carrying out subsection (a), the Secretary shall consult with the Public Health Emergency Medical Countermeasures Enterprise established under section 2811–1.

''(d) PUBLICATION OF LIST.—The Secretary shall—

''(1) not later than 180 days after the date of enactment of this section, publish a preliminary list of priority medicines;

''(2) provide an opportunity for public comment on such preliminary list;

''(3) not later than 1 year after such date of enactment, publish a final list of priority medicines; and

''(4) on an annual basis, review and, as appropriate, update such list.

''(e) DEFINITIONS.—In this section:

''(1) ACTIVE PHARMACEUTICAL INGREDIENT.—The term 'active pharmaceutical ingredient'—

''(A) means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of a disease, or to affect the structure or any function of the body of a human or animal; and

''(B) does not include—

''(i) intermediates used in the synthesis of a drug product; or

''(ii) components that may undergo chemical change in the manufacture of a drug product and be present in a drug product in a modified form that is intended to furnish such activity or effect.

''(2) COVERED PRODUCT.—The term 'covered product' means a drug (including a biological product) or an active pharmaceutical ingredient.

''(3) PRIORITY MEDICINE.—The term 'priority medicine' means a priority medicine for which a designation is in effect under subsection (a).''.

(b) NATIONAL STRATEGIC HEALTH STRATEGY.—Section 2802(b) of the Public Health Service Act (42

U.S.C. 300hh–1(b)) is amended by adding at the end the following:

''(11) PRIORITY MEDICINES.—Supporting the identification, production, and procurement of priority medicines designated under section 2804.''.

(c) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE RECOMMENDATIONS.—Section 2811–1(c)(1) of the Public Health Service Act (42 U.S.C. 300hh–10a(c)) is amended by adding at the end the following:

''(E) Provide recommendations to the Secretary with respect to the priority medicines designated under section 2804.''.

(d) STRATEGIC PLAN FOR COUNTERMEASURE RESEARCH, DEVELOPMENT, AND PROCUREMENT.—Section 319L(b) of the Public Health Service Act (42 U.S.C. 247d–7e(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (B), by striking ''and'' at the end;

(B) in subparagraph (C), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(D) the development and procurement of priority medicines designated under section 2804.''; and

(2) by adding at the end the following:

''(3) PRIORITY MEDICINES.—With respect to the development and procurement of priority medicines, the Secretary shall promote a diverse and sustainable supply chain, including through grants and purchases.''.

(e) CRITICAL DRUG CONSIDERATION.—Section 3101 of the CARES Act (Public Law 116–136) is amended—

(1) by redesignating subsection (d) as subsection (e); and

(2) after executing the redesignation in paragraph (1), by inserting after subsection (c) the following:

''(d) CONSIDERATION.—With respect to any analysis of a critical drug under subsection (b)(1), the Secretary shall consider the vulnerability of such drug with respect to the global supply chain, including an analysis of—

''(1) the number of manufacturers of such drug;

''(2) the manufacturing locations, and amounts produced, of such drug;

''(3) the history of the importation of such drug; and

''(4) the probability of the imposition of duties on the importation of such drug.''.

SEC. 4. PRIORITY MEDICINE PRODUCTION CREDIT.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

''SEC. 45U. PRIORITY MEDICINE PRODUCTION CREDIT.

''(a) GENERAL RULE.—For purposes of section 38, the priority medicine production credit determined under this section for the taxable year is an amount equal to 50 percent of the qualified priority medicine expenses for the taxable year.

''(b) QUALIFIED PRIORITY MEDICINE EXPENSES.—

''(1) QUALIFIED PRIORITY MEDICINE EXPENSES.—The term 'qualified priority medicine expenses' means direct and indirect costs paid or incurred by the taxpayer during the taxable year for the production of priority medicines.

''(2) PRIORITY MEDICINES.—For purposes of this section, a 'priority medicine' is a medicine that was included, within the 5 calendar years immediately preceding the taxable year, on the list devel-

oped and published by the Secretary of Health and Human Services pursuant to section 2804(d) of the Public Health Service Act.

''(3) COORDINATION WITH SECTION 263A.—

''(A) COORDINATION WITH SECTION 263A.—In applying section 263A, indirect costs shall be allocated between the production of priority medicines and the production of other medicines based on the ratio in which the number of doses of the priority medicines produced in the taxable year bears to the total number of doses of all medicines produced by the taxpayer in that taxable year to which the expense is attributable.

''(B) REGULATIONS AND GUIDANCE.—The Secretary shall by regulation or other guidance prescribe rules for the proper allocation of indirect costs described in subparagraph (A).''.

(b) CREDIT ALLOWED AS BUSINESS CREDIT.—Section 38(b) of the Internal Revenue Code of 1986 (relating to current year business credit) is amended by striking ''plus'' at the end of paragraph (32), by striking the period at the end of paragraph (33) and inserting '', plus'', and adding at the end the following new paragraph:

''(34) the priority medicine production credit determined under section 45U.''.

(c) CONFORMING AMENDMENTS.—

(1) COORDINATION WITH SECTION 59.—

(A) Section 59A(b)(1)(B)(ii) is amended—

(i) in subclause (I), by striking ''plus,'' at the end;

(ii) in subclause (II), by striking the period at the end, and inserting '', plus''; and

(iii) by adding at the end the following:

''(III) the credit allowed under section 38 for the taxable year which is properly allocable to the priority medicine production credit determined under section 45U.''.

(B) Section 59A(b)(2)(B) is amended to read as follows:

''(B) by reducing (but not below zero) the regular tax liability (as defined in section 26(b)) for purposes of subparagraph (B) thereof by the excess (if any) of the aggregate amount of the credits allowed under this chapter against such regular tax liability over the

credit allowed under section 38 for the taxable year which is properly allocable to the priority medicine production credit determined under section 45U, rather than the excess described in such paragraph.''.

(2) COORDINATION WITH RESEARCH CREDIT.—Section 41(c)(4)(A) is amended by striking ''14'' and inserting ''20''.

(d) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by inserting after the item relating to section 45T the following new item:

''Sec. 45U. Priority medicine production credit.''

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to qualified priority medicine expenses paid or incurred after December 31, 2020.

SEC. 5. IMPROVING REGULATORY EFFICIENCIES FOR TRANSFER OF DRUGS.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by inserting after section 505–1 of such Act (21 U.S.C. 355–1) the following:

''SEC. 505–2. TRANSFER OF DRUGS TO DOMESTIC ESTABLISHMENTS.

''(a) IN GENERAL.—Beginning not later than 90 days after the date of the enactment of this section, the

Secretary shall expedite the review and approval of a supplemental application to an abbreviated new drug application approved under section 505(j) or a new drug application approved under section 505(c) that seeks to transfer manufacturing of one or more finished dosage forms of a drug or one or more active pharmaceutical ingredients therein from one or more foreign establishments to one or more new or existing domestic establishments.

''(b) BEFORE SUPPLEMENTAL APPLICATION SUBMISSION.—

''(1) DEVELOPMENT AND PRE-SUBMISSION.—After an applicant submits a meeting request with respect to expedited review and approval of a supplemental application pursuant to subsection (a), the Secretary shall—

''(A) not later than 30 days after receiving such request, conduct a meeting with the applicant to—

''(i) discuss the information necessary to approve the supplemental application; and

''(ii) if applicable, schedule a pre-approval inspection; and

''(B) not later than 60 days after receiving such request, conduct a meeting with the applicant to—

''(i) provide advice to the applicant with respect to the supplemental application; and

''(ii) if applicable, select a first drug to be identified in accordance with subsection (c).

''(2) REVIEW AND APPROVAL.—In carrying out subsection (a), the Secretary shall—

''(A) review and take action with respect to a supplemental application not later than 6 months after the date of submission or resubmission of such application; and

''(B) where the Secretary recommends a change to a domestic establishment following an inspection of such establishment, reinspect the establishment not later than 90 days after receiving a request from the applicant for reinspection.

''(3) RELATION TO FEE PERFORMANCE GOALS.—The deadlines specified in paragraph (1) supersede any conflicting performance goals identified in any statute reauthorizing the fee programs in

parts 2 and 7 of subchapter C of title VII of the Federal Food, Drug, and Cosmetic Act.

''(c) CONTENTS.—With respect to a supplemental application under subsection (a) for a transfer of the site of manufacture of multiple drugs that share a similar manufacturing process, the Secretary shall—

''(1) request a list of the drugs;

''(2) from the list under paragraph (1), identify a first drug to be transferred;

''(3) determine the criteria necessary to receive approval of the supplemental application; and

''(4) require the applicant to demonstrate, as part of such criteria, that each foreign establishment from which the drugs are to be transferred has a satisfactory inspection history with respect to the drugs.

''(d) SUBSEQUENT TRANSFER OF DRUGS THAT SHARE A SIMILAR MANUFACTURING PROCESS.—After the approval of a supplemental application under subsection (a) for the transfer of the manufacturing of a first drug identified by the Secretary pursuant to subsection (c)(2) from one or more foreign establishments to one or more new or existing domestic establishments, the Secretary may allow the applicant to so transfer drugs that share a similar manufacturing process with such first drug pur-

suant to submission of a report under section 506A(d)(2) rather than by requiring submission of a supplemental application.

''(e) WORKING GROUP.—

''(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this section, the Secretary shall establish an intra-agency working group to be known as the Facility Transfer Working Group.

''(2) MEMBERSHIP.—The Secretary shall appoint members of the Facility Transfer Working Group from among officials and employees of the Department of Health and Human Services who—

''(A) represent a cross-section of the Department of Health and Human Services; and

''(B) have expertise on establishments used to manufacture drugs.

''(3) DUTIES.—The Facility Transfer Working Group shall—

''(A) assist the Secretary in carrying out this section;

''(B) upon request by an applicant, conduct an informational site visit during the developmental phase to discuss requirements with

the applicant with respect to facility design, site status, and validation;

''(C) not later than 30 days after conducting an informational site visit under subparagraph (B), provide advice and feedback to the applicant with respect to facility issues that may prevent approval of the supplemental application under subsection (a), including any issues with the facility transfer plans; and

''(D) participate in any pre-approval inspection required by the Secretary for an establishment or provide feedback to the Secretary with respect to a supplemental application described in subsection (a).

''(f) ADDITIONAL INFORMATIONAL VISITS.—Upon request by the applicant, the Secretary may conduct informational site visits in addition to an informational site visit conducted by the Facility Transfer Working Group under subsection (e).

''(g) GUIDANCE.—

''(1) ISSUANCE.—Not later than 1 year after the date of enactment of this section, the Secretary shall issue guidance with respect to this section.

''(2) CONTENT.—The guidance issued under this paragraph shall include—

''(A) the process by which an applicant may seek expedited review and approval of a supplemental application under subsection (a); and

''(B) a description of the actions the Secretary may take to expedite the submission and review of such supplemental application.

''(h) DEFINITIONS.—In this section:

''(1) SATISFACTORY INSPECTION HISTORY.—The term 'satisfactory inspection history' means, with respect to a drug, a history consisting of one or more inspections in which the most recent manufacturing inspection was a satisfactory manufacturing inspection during which—

''(A) no objectionable conditions or practices were found; or

''(B) objectionable conditions were found and voluntary corrective action was left to the manufacturer.

''(2) SIMILAR MANUFACTURING PROCESS.—The term 'similar manufacturing process' means processes used to manufacture drugs that share at least one unit operation having the same design principle.''.